Public Assessment Report
ADAFIMAB

INFORMASI PRODUK

Nama obat	:	Adafimab
Bentuk sediaan	:	Injeksi
Zat aktif	:	Adalimumab 40 mg/0,8 mL
Kemasan	:	Dus, 1 pre-filled syringe @ 0,8 mL
Pemilik Ijin Edar	:	PT. Infion
Produsen	:	Suzhou Union Biopharm Co., Ltd, Suzhou, China untuk Mabwell (Shanghai) Bioscience Co, Ltd, Shanghai, China
Kategori Registrasi	:	Produk Biosimilar Baru
Indikasi yang diajukan:	:	*Rheumatoid arthritis* *Adafimab is indicated for reducing signs and symptoms, inducing major clinical response and clinical remission, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA).* *Adafimab can be used alone or in combination with Methotrexate or other disease modifying anti-rheumatic drugs (DMARDs).* *Axial spondyloarthritis* *• Ankylosing spondylitis* *Adafimab is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis (AS).* *• Non-radiographic axial spondyloarthritis (axial spondyloarthritis without radiographic evidence of AS)* *Adafimab is indicated for reducing signs and symptoms in patients with active non-radiographic axial spondyloarthritis.* *Plaque psoriasis* *Adafimab is indicated for moderate to severe chronic plaque psoriasis with or without moderate or severe nail psoriasis in adult patients who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate. Adafimab is indicated for moderate to severe nail psoriasis in adult patients who are candidates for systemic therapy.* *Crohn's disease* *Adafimab is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease (CD) who have had an inadequate response to conventional therapy. Adafimab is indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to Infliximab.* *Hidradenitis Suppurativa* *Adafimab is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adult patients, whose lesion were present in at least 2 distinct anatomic areas one of which was Hurley Stage II or Hurley Stage III, had an inadequate response to at least a 3-month (90 days) trial of oral antibiotics for treatment of HS, had stable HS for at least 2 months, and had a negative TB or systemic infection* *Uveitis* *Adafimab is indicated for the treatment of non-infectious intermediate, posterior, and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate.* *Polyarticular juvenile idiopathic arthritis* *Adafimab in combination with Methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in children and adolescents aged 4 to 17 years*

who have had an inadequate response to NSAID, steroid, one or more disease-modifying antirheumatic drugs (DMARDs). Adafimab should only be administered to patients who will be closely monitored and have regular follow up visits with physician. Adafimab should not be used as initial treatment.

Posologi yang diajukan : *DOSAGE AND ADMINISTRATIONS :*

Adafimab is administered by subcutaneous injection.

Dosage

Rheumatoid arthritis, Psoriatic Arthritis, and axial spondyloarthritis (ankylosing spondylitis and non-radiographic axial spondyloarthritis)

The recommended dose of Adafimab for adult patients with rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis (ankylosing spondylitis and non-radiographic axial Spondyloarthritis) is 40 mg administered every other week as a single dose via subcutaneous injection. Methotrexate, glucocorticoids, salicylates, nonsteroidal anti-inflammatory drugs, analgesics or other DMARDs may be continued during treatment with Adafimab.

In rheumatoid arthritis, some patients not taking concomitant Methotrexate may derive additional benefit from increasing the dosing frequency of Adafimab to 40 mg every week (optional).

Plaque psoriasis

The recommended dose of Adafimab for adult patients with plaque psoriasis is an initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose.

The use of Adafimab in moderate to severe chronic plaque psoriasis beyond one year has not been evaluated in controlled clinical studies.

The use of Adafimab in moderate to severe chronic plaque psoriasis beyond one year has not been evaluated in controlled clinical studies.

Crohn's disease

The recommended Adafimab dose regimen for adult patients with Crohn's disease is 160 mg initially at Day 1 (given as four 40 mg injections in one day or as two 40 mg injections per day for two consecutive days), followed by 80 mg two weeks later (Day 15). Another two weeks later (Day 29) begin a maintenance dose of 40 mg every other week. Aminosalicylates, corticosteroids, and/or immunomodulatory agents (e.g., 6-Mercaptopurine and Azathioprine) may be continued during treatment with Adafimab.

Some patients who have not responded by week 4 may benefit from continued maintenance therapy through week 12. Continued therapy should be carefully reconsidered in a patient not responding within this time period.

During maintenance treatment, corticosteroids may be tapered in accordance with clinical practice guidelines.

The use of Adafimab in Crohn's disease beyond one year has not been evaluated in controlled clinical studies.

Hidradenitis Suppurativa

The recommended Adafimab dose regimen for adult patients with Hidradenitis Suppurativa (HS) is 160 mg initially at Day 1 (given as four 40 mg injections in one day

or as two 40 mg injections per day for two consecutive days), followed by 80 mg two weeks later at Day 15 (given as two 40 mg injections in one day). Two weeks later (Day 29) continue with a dose of 40 mg every week. Antibiotics should be continued during treatment with Adafimab. Should treatment need to be interrupted, Adafimab may be reintroduced. In patients without any benefit after 12 weeks of treatment, continued therapy should be reconsidered.

Uveitis

The recommended dose of Adafimab for adult patients with uveitis is an initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose.

There is limited experience in the initiation of treatment with Adalimumab alone. Treatment with Adafimab can be initiated in combination with corticosteroids and/or with other non-biologic immunomodulatory agents.

Concomitant corticosteroids may be tapered in accordance with clinical practice starting two weeks after initiating treatment with Adafimab.

It is recommended that the benefit and risk of continued long-term treatment should be evaluated on a yearly basis

<u>Paediatric Population</u>

Polyarticular juvenile idiopathic arthritis

Note: The clinical study to support the indication was done using a dose by body surface area throughout the controlled phase. In the open label part of the study, the dosing was changed to a fixed dose according to a body weight cut-off.

The FDA recommended dose of Adalimumab for patients 4 to 17 years of age with polyarticular juvenile idiopathic arthritis is based on weight as shown below. Methotrexate, glucocorticoids, salicylates, NSAIDs or analgesics may be continued during treatment with Adafimab.

Pediatric Patients (4 to 17 years)	*Dose*
15 kg to < 30 kg	*20 mg every other week*
≥ 30 kg	*40 mg every other week*

Adalimumab has not been studied in children aged less than 4 years. Limited data are available for Adalimumab treatment in pediatric patients with a weight below 15 kg.

The recommended dose of Adafimab for patients with polyarticular juvenile idiopathic arthritis in the EU:

- *Polyarticular juvenile idiopathic arthritis age 4 to 12 years*

The recommended dose of Adafimab for patients with polyarticular juvenile idiopathic arthritis, aged 4 to 12 years, is 24 mg/m^2 body surface area up to a maximum single dose of 40 mg Adalimumab administered every other week via subcutaneous injection. The volume for injection is selected based on the patients height and weight (as shown in table below). A 40 mg pediatric vial is available for patients who need to administer less than the full 40 mg dose.

Adafimab dose in mililiters (ml) by height and weight of children for polyarticular juvenile idiopathic arthritis

Height (cm)	*Total Body Weight (kg)*												
	10	*15*	*20*	*25*	*30*	*35*	*40*	*45*	*50*	*55*	*60*	*65*	*70*
80	*0.2*	*0.3*	*0.3*	*0.3*									
90	*0.2*	*0.3*	*0.3*	*0.4*	*0.4*	*0.4*							
100	*0.3*	*0.3*	*0.3*	*0.4*	*0.4*	*0.4*	*0.5*	*0.5*					
110	*0.3*	*0.3*	*0.4*	*0.4*	*0.4*	*0.5*	*0.5*	*0.5*	*0.5*	*0.6*	*0.6*		
120	*0.3*	*0.4*	*0.4*	*0.4*	*0.5*	*0.5*	*0.5*	*0.6*	*0.6*	*0.6*	*0.6*	*0.7*	*0.7*
130		*0.4*	*0.4*	*0.5*	*0.5*	*0.5*	*0.6*	*0.6*	*0.6*	*0.6*	*0.7*	*0.7*	*0.7*
140		*0.4*	*0.4*	*0.5*	*0.5*	*0.6*	*0.6*	*0.6*	*0.7*	*0.7*	*0.7*	*0.7*	*0.8*
150			*0.5*	*0.5*	*0.6*	*0.6*	*0.6*	*0.7*	*0.7*	*0.7*	*0.7*	*0.8*	*0.8*
160			*0.5*	*0.5*	*0.6*	*0.6*	*0.7*	*0.7*	*0.7*	*0.8*	*0.8*	*0.8*	*0.8*
170				*0.6*	*0.6*	*0.6*	*0.7*	*0,7*	*0.8*	*0.8*	*0.8*	*0.8*	*0.8*
180					*0.6*	*0.7*	*0.7*	*0.8*	*0.8*	*0.8*	*0.8*	*0.8*	*0.8*
**Maximum single dose is 40 mg (0.8 ml)*													

- *Polyarticular juvenile idiopathic arthritis age 13 to 17 years*

For adolescents aged 13 to 17 years, a dose of 40 mg administered every other week is administered regardless of body surface area.

Available data suggest that clinical response is usually achieved within 12 weeks of treatment.

PENGANTAR

Adafimab merupakan produk Biosimilar adalimumab dengan innovator Humira. Adafimab merupakan antibodi monoklonal rekombinan yang bekerja dengan cara menghambat tumor necrosis factor-α (TNF-α). Adalimumab berfungsi dengan mengikat TNF-α dan menghambat aktivitas biologisnya, sehingga dapat mengurangi proses peradangan. Oleh karena itu, Adafimab digunakan dalam pengobatan rheumatoid arthritis dan penyakit autoimun lainnya, baik sebagai terapi tunggal maupun dikombinasikan dengan metotreksat, untuk membantu mengurangi nyeri dan pembengkakan.

ASPEK MUTU

Adafimab mengandung zat aktif adalimumab yang merupakan antibodi monoklonal rekombinan tipe. Adafimab disintesis menggunakan teknologi DNA rekombinan pada sel Chinese Hamster Ovary (CHO).

Zat Aktif

Adafimab mengandung adalimumab yang diproduksi di Suzhou Union Biopharm Co. Ltd,.China.
Kontrol selama proses produksi zat aktif telah dilakukan dengan baik dan memenuhi spesifikasi yang telah ditetapkan. Karakterisasi zat aktif telah dilakukan secara memadai dan didukung oleh spesifikasi yang sesuai.

Obat jadi

Adafimab tersedia dalam bentuk sediaan *solution for injection* dengan kekuatan 40 mg/syringe (0,8mL). Pengembangan proses pembuatan obat telah dilakukan mulai dari bets uji klinik hingga bets komersil. Adafimab merupakan produk biosimilar, sehingga dilakukan studi komparabilitas dengan produk inovator untuk membuktikan kesebandingan (similaritas). Hasil studi menunjukkan bahwa Adafimab similar terhadap produk inovator. Proses produksi obat meliputi thawing, pencampuran bahan obat, filtrasi steril, unpacking, pengisian dan penutupan dengan stopper. Adafimab diproduksi secara aseptis dan kontrol selama proses produksi dilakukan untuk menjamin mutu produk yang dihasilkan. Kajian terhadap FI VI telah dilakukan secara komprehensif. Kemasan Produk jadi prefilled syringe. Data stabilitas yang diserahkan menunjang klim shelf-life yaitu hingga 24 bulan pada kondisi penyimpanan 2^{o}C-8^{o}C.

Kesimpulan

Berdasarkan data mutu Adafimab yang diserahkan baik produksi zat aktif dan produk jadi telah dikontrol dengan baik mulai dari bahan baku, selama proses pembuatan, hingga tahap akhir sehingga dapat menghasilkan produk yang memenuhi spesifikasi pelulusan dan shelf-life, serta menunjukkan profil mutu yang sebanding dengan inovator.

ASPEK KHASIAT DAN KEAMAAN

Data Non Klinik

1. Studi invitro binding activity dan TNF—alpha Receptor Blocking Effect menunjukkan profil yang sebanding dengan Humira
2. Studi farmakodinamik invivo pada hTNF-alpha Transgenic Mice menunjukkan efek protektif terhadap arthritis sebanding dengan Humira dan aktivitas perlindungan bergantung pada dosis yang diberikan (dose-dependent)
3. Pemberian 33 mg/kg selama 4 minggu pada Cynomolgus monkey menunjukkan bahwa nilai Cmax dan AUC nya similar dengan Humira
4. Toksikologi
   a. Toksisitas dosis tunggal dievaluasi setelah pemberian dosisi 1000 mg/kg pada tikus sprague dawley menunjukkan tidak ada abnormalitas teramati baik pada kelompok uji maupun kelompok kontrol
   b. Toksisitas dosis tunggal pada Cynomolgus monkeys menunjukkan NOAEL pemberian injeksi subkutan adalah 267 mg/kg dan dosis toksisnya adalah 400 mg/kg.
   c. Toksisitas berulang pada Cynomolgus monkeys menunjukkan bahwa NOAEL pemberian injeksi subkutan berulang adalah 200 mg/kg dan profil toksisitasnya sebanding dengan Humira. ADA terdeteksi pada hari ke-28 setelah pemberian dan profilnya sebanding dengan Humira.

Data Klinik

Diserahkan dokumen untuk penilaian aspek efikasi keamanan sebagai berikut:

a. Studi Fase I, bertujuan menilai farmakokinetik, n=182, subjek sehat
b. Studi fase III bertujuan menilai efikasi keamanan pada pasien moderate to severe active Rheumatoid Arthritis (n=261)
c. Periodic Benefit Risk Evaluation Report (PBRER) Periode 1 Maret 2022 – 30 Mei 2023
d. Risk Management Plan (RMP) tahun 2019

Hasil evaluasi terhadap studi di atas yaitu

1. Farmakokinetik/Farmakodinamik klinik
   - Hasil studi farmakokinetik klinik (studi fase I, n= 182 subjek sehat) dan fase III pada pasien rheumatoid arthritis menunjukkan profil
   - farmakokinetik Adafimab sebanding dengan Humira berdasarkan parameter Cmax, AUC0-t dan AUC0-~.Tidak ada studi farmakodinamik khusus, tetapi dijustifikasi bahwa farmakodinamik diestimasi sebagai efikasi di studi klinik fase III.
2. Efikasi dan keamanan klinik
   - Studi pivotal fase III pada pasien moderate to severe active Rheumatoid Arthritis menunjukkan efikasi dan keamanan yang sebanding antara kelompok Adafimab (n=263) dengan Humira (n=261) sebagai berikut :
     - Efikasi Adafimab dan Humira sebanding berdasarkan parameter efikasi primer ACR20 pada minggu ke-24.
     - Parameter efikasi sekunder, yaitu ACR50 response rate, ACR70 response rate dan DAS28-CRP remission rate pada minggu ke-24 juga menunjukkan hasil yang sebanding antara Adafimab vs Humira.
     - Data keamanan menunjukkan bahwa secara umum profil keamanan sebanding antara Adafimab dan Humira. Tidak ada kematian yang dilaporkan selama studi. Profil imunogenisitas sebanding antara kelompok obat uji dan kelompok Humira.
   - Ekstrapolasi indikasi
     Ekstrapolasi untuk indikasi-indikasi yang diajukan, termasuk untuk populasi anak, dapat dipertimbangkan karena obat mempunyai mekanisme yang sama untuk semua indikasi yang terkait dengan penekanan sistem imun.

Kesimpulan hasil evaluasi

1. Hasil studi farmakokinetik klinik (fase I) menunjukkan profil farmakokinetik Adafimab sebanding dengan Humira berdasarkan parameter Cmax, AUC0-t dan AUC0-~
2. Studi pivotal fase III pada pasien *moderate to severe active Rheumatoid Arthritis* menunjukkan efikasi adafimab dan Humira sebanding berdasarkan parameter efikasi primer ACR20 pada minggu ke-24.
3. Parameter efikasi sekunder, yaitu ACR50 response rate, ACR70 response rate dan

DAS28-CRP remission rate pada minggu ke-24 juga menunjukkan hasil yang sebanding antara Adafimab vs Humira.

4. Data keamanan menunjukkan bahwa secara umum profil keamanan sebanding antara Adafimab dan Humira. Tidak ada kematian yang dilaporkan selama studi. Profil imunogenisitas sebanding antara kelompok obat uji dan kelompok Humira.

EVALUASI

Penilaian Manfaat-Risiko

Adafimab mengandung Adalimumab yang merupakan merupakan antibodi monoklonal rekombinan yang bekerja dengan cara menghambat tumor necrosis factor-α (TNF-α). Adalimumab berfungsi dengan mengikat TNF-α dan menghambat aktivitas biologisnya, sehingga dapat mengurangi proses peradangan. Oleh karena itu, Adafimab digunakan dalam pengobatan rheumatoid arthritis dan penyakit autoimun lainnya, baik sebagai terapi tunggal maupun dikombinasikan dengan metotreksat, untuk membantu mengurangi nyeri dan pembengkakan. Obat ini harus disimpan pada suhu dingin (2-8°C).

Berdasarkan data mutu yang diserahkan, produksi zat aktif dan produk jadi Adafimab telah dikontrol dengan baik mulai dari bahan baku, selama proses pembuatan, hingga tahap akhir sehingga dapat menghasilkan produk vaksin yang memenuhi spesifikasi pelulusan dan shelf-life.

Berdasarkan data khasiat dan keamanan yang diperoleh dari hasil studi non klinik dan klinik, Adafimab memiliki efek yang menguntungkan, efek yang tidak menguntungkan, ketidakpastian dan keterbatasan sebagai berikut:

a. Aspek yang menguntungkan:
   i. Efikasi Adafimab dan Humira sebanding berdasarkan parameter efikasi primer ACR20 pada minggu ke-24.
   ii. Efikasi Adafimab dan Humira sebanding berdasarkan Parameter efikasi sekunder, yaitu ACR50 response rate, ACR70 response rate dan DAS28-CRP remission rate pada minggu ke-24 juga menunjukkan hasil yang sebanding.
   iii. Kejadian AE yang menyebabkan penghentian obat sebanding dengan inovator
b. Aspek yang tidak menguntungkan :
   i. Kejadian ADA positif pada minggu ke-24 lebih tinggi pada Adafimab dibandingkan dengan Humira.
   ii. Kejadian ADR yang paling sering dilaporkan yaitu : Infection and infestations, Investigations, upper respiratory tract infection, Hepatobiliary disorders.
c. Ketidakpastian dan keterbatasan :
   i. Tidak ada data untuk pasien dengan immunodeficiency
   ii. Tidak ada data penggunaan pada wanita hamil dan menyusui

d. Kesimpulan evaluasi risiko-manfaat:
   Secara keseluruhan Adafimab menunjukkan kemanfaatan dalam pengobatan Rheumatoid arthritis, Psoriatic arthritis, Axial spondyloarthritis, Plaque psoriasis, Crohn's disease, Ulcerative colitis, Hidradenitis suppurativa, Uveitis, Polyarticular juvenile idiopathic arthritis dan profil keamanan Adafimab sebanding dengan produk inovator (Humira)

KEPUTUSAN

Mempertimbangkan data khasiat dan keamanan tersebut di atas, diputuskan registrasi produk biosimilar Adafimab dapat disetujui dengan indikasi dan posologi sesuai dengan produk inovator (Humira) sebagai berikut:

Indication

Rheumatoid arthritis

Adafimab is indicated for reducing signs and symptoms, inducing major clinical response and clinical remission, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA).
Adafimab can be used alone or in combination with Methotrexate or other disease modifying anti-rheumatic drugs (DMARDs).

Psoriatic arthritis

Adafimab is indicated for reducing the signs and symptoms of active arthritis in patients with psoriatic arthritis (PsA). Adafimab has been shown to reduce the rate of progression of peripheral joint damage as measured by X- ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function.

Adafimab can be used alone or in combination with DMARDs.

Axial spondyloarthritis

Ankylosing spondylitis
Adafimab is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis (AS).
Non-radiographic axial spondyloarthritis (axial spondyloarthritis without radiographic evidence of AS)
Adafimab is indicated for reducing signs and symptoms in patients with active non- radiographic axial spondyloarthritis
subtypes of the disease and to improve physical function.
Adafimab can be used alone or in combination with DMARDs.
Axial spondyloarthritis
• Ankylosing spondylitis
Adafimab is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis (AS).
• Non-radiographic axial spondyloarthritis (axial spondyloarthritis without radiographic evidence of AS)
Adafimab is indicated for reducing signs and symptoms in patients with active non-radiographic axial spondyloarthritis
Plaque psoriasis
Adafimab is indicated for moderate to severe chronic plaque psoriasis with or without moderate or severe nail psoriasis in adult patients who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate. Adafimab is indicated for moderate to severe nail psoriasis in adult patients who are candidates for systemic therapy.

Crohn's disease

Adafimab is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease (CD) who have had an inadequate response to conventional therapy. Adafimab is indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to Infliximab.

Ulcerative colitis

Adafimab is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who had an inadequate response to conventional therapy including corticosteroids and/or 6-Mercaptopurine (6-MP) or Azathioprine (AZA). The conventional therapy must be continued concurrently with Adafimab. Corticosteroids can be tappered down after 8 weeks of Adafimab administration.

Hidradenitis Suppurativa

Adafimab is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adult patients, whose lesion were present in at least 2 distinct anatomic areas

The recommended Adafimab dose regimen for adult patients with Hidradenitis Suppurativa (HS) is 160 mg initially at Day 1 (given as four 40 mg injections in one day or as two 40 mg injections per day for two consecutive days), followed by 80 mg two weeks later at Day 15 (given as two 40 mg injections in one day). Two weeks later (Day 29) continue with a dose of 40 mg every week. Antibiotics should be continued during treatment with Adafimab. Should treatment need to be interrupted, Adafimab may be reintroduced. In patients without any benefit after 12 weeks of treatment, continued therapy should be reconsidered.

Uveitis

The recommended dose of Adafimab for adult patients with uveitis is an initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose. There is limited experience in the initiation of treatment with Adalimumab alone. Treatment with Adafimab can be initiated in combination with corticosteroids and/or with other nonbiologic immunomodulatory agents.

Concomitant corticosteroids may be tapered in accordance with clinical practice starting two weeks after initiating treatment with Adafimab.

It is recommended that the benefit and risk of continued long-term treatment should be evaluated on a yearly basis.

Polyarticular juvenile idiopathic arthritis

Note: The clinical study to support the indication was done using a dose by body surface area throughout the controlled phase. In the open label part of the study, the dosing was changed to a fixed dose according to a body weight cut-off.

The FDA recommended dose of Adalimumab for patients 4 to 17 years of age with polyarticular juvenile idiopathic arthritis is based on weight as shown below. Methotrexate, glucocorticoids, salicylates, NSAIDs or analgesics may be continued during treatment with Adafimab.

Pediatric Patients (4 to 17 years)	*Dose*
15 kg to < 30 kg	*20 mg every other week*
≥ 30 kg	*40 mg every other week*

Adalimumab has not been studied in children aged less than 4 years. Limited data are available for Adalimumab treatment in pediatric patients with a weight below 15 kg.

The recommended dose of Adafimab for patients with polyarticular juvenile idiopathic arthritis in the EU:

Polyarticular juvenile idiopathic arthritis age 4 to 12 years

The recommended dose of Adafimab for patients with polyarticular juvenile idiopathic arthritis, aged 4 to 12 years, is 24 mg/m^2 body surface area up to a maximum single dose of 40 mg Adalimumab administered every other week via subcutaneous injection. The volume for injection is selected based on the patients height and weight (as shown in table below). A 40 mg pediatric vial is available for patients who need to administer less than the full 40 mg dose.

Adafimab dose in mililiters (ml) by height and weight of children for polyarticular juvenile idiopathic arthritis

Height (cm)	*Total Body Weight (kg)*												
	10	*15*	*20*	*25*	*30*	*35*	*40*	*45*	*50*	*55*	*60*	*65*	*70*
80	*0.2*	*0.3*	*0.3*	*0.3*									
90	*0.2*	*0.3*	*0.3*	*0.4*	*0.4*	*0.4*							
100	*0.3*	*0.3*	*0.3*	*0.4*	*0.4*	*0.4*	*0.5*	*0.5*					
110	*0.3*	*0.3*	*0.4*	*0.4*	*0.4*	*0.5*	*0.5*	*0.5*	*0.5*	*0.6*	*0.6*		
120	*0.3*	*0.4*	*0.4*	*0.4*	*0.5*	*0.5*	*0.5*	*0.6*	*0.6*	*0.6*	*0.6*	*0.7*	*0.7*
130		*0.4*	*0.4*	*0.5*	*0.5*	*0.5*	*0.6*	*0.6*	*0.6*	*0.6*	*0.7*	*0.7*	*0.7*
140		*0.4*	*0.4*	*0.5*	*0.5*	*0.6*	*0.6*	*0.6*	*0.7*	*0.7*	*0.7*	*0.7*	*0.8*
150			*0.5*	*0.5*	*0.6*	*0.6*	*0.6*	*0.7*	*0.7*	*0.7*	*0.7*	*0.8*	*0.8*
160			*0.5*	*0.5*	*0.6*	*0.6*	*0.7*	*0.7*	*0.7*	*0.8*	*0.8*	*0.8*	*0.8*
170				*0.6*	*0.6*	*0.6*	*0.7*	*0,7*	*0.8*	*0.8*	*0.8*	*0.8*	*0.8*
180					*0.6*	*0.7*	*0.7*	*0.8*	*0.8*	*0.8*	*0.8*	*0.8*	*0.8*
**Maximum single dose is 40 mg (0.8 ml)*													

Polyarticular juvenile idiopathic arthritis age 13 to 17 years

For adolescents aged 13 to 17 years, a dose of 40 mg administered every other week is administered regardless of body surface area.

Available data suggest that clinical response is usually achieved within 12 weeks of treatment.